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NOTICE OF ALLOWANCE AND FEE(S) DUE

23552

7590

03/10/2008

MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 EXAMINER

GAMETT, DANIEL C

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/10/2008

| APPL | ICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------|-------------|-------------|-----------------------|---------------------|------------------|
| 1 | 0/088,950 | 03/20/2002 | Frederic J de Sauvage | 11669.0123USWO | 4737 |

TITLE OF INVENTION: MODULATION OF T CELL DIFFERENTIATION FOR THE TREATMENT OF T HELPER CELL MEDIATED DISEASES

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1440 | \$0 | \$1440 | \$1440 | 06/10/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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| 23552 MERCHANT 6 P.O. BOX 2903 MINNEAPOLIS | | /2008 | | Cortif | icate of Mailing or Tran | smission g deposited with the United st class mail in an envelope above, or being facsimile date indicated below. | |
| | | | | | | (Depositor's name) | |
| | | | _ | | | (Signature) | |
| | _ | | | | | (Date) | |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | Α | TTORNEY DOCKET NO. | CONFIRMATION NO. | |
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| GAMETT, | DANIEL C | 1647 | 424-144100 | J | | | |
| 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. | | | (1) the names of up to or agents OR, alternative (2) the name of a single registered attorney or a 2 registered patent attorney or a 3 registered patent attorney or 3 r | the names of up to 3 registered patent attorneys gents OR, alternatively, the name of a single firm (having as a member a astered attorney or agent) and the names of up to gistered patent attorneys or agents. If no name is ed, no name will be printed. | | | |
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| | tus (from status indicate s SMALL ENTITY state | | ☐ b. Applicant is no lon | ger claiming SMALL | ENTITY status. See 37 C | CFR 1.27(g)(2). | |
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| an application. Confident submitting the completed this form and/or suggesti | tiality is governed by 35 d application form to the ions for reducing this but firginia 22313-1450. DC | U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th | 1.14. This collection is est depending upon the indivite Chief Information Office | imated to take 12 min ridual case. Any com- er, U.S. Patent and Tr | nutes to complete, includi ments on the amount of ti ademark Office, U.S. Der | d by the USPTO to process) ng gathering, preparing, and me you require to complete partment of Commerce, P.O. for Patents, P.O. Box 1450, | |

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

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| MERCHANT & | GOULD PC | GAMETT, DANIEL C | | |
| P.O. BOX 2903 | | ART UNIT | PAPER NUMBER | |
| MINNEAPOLIS, MN 55402-0903 | | | 1647 | |
| | | DATE MAILED: 03/10/2008 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 190 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 190 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

| | Application No. | Applicant(s) | |
|--|--|---|--|
| | 10/088,950 | DE SAUVAGE ET AL. | |
| Notice of Allowability | Examiner | Art Unit | |
| | DANIEL C. GAMETT | 1647 | |
| The MAILING DATE of this communication apperature All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313 | ears on the cover sheet with th (OR REMAINS) CLOSED in this or other appropriate communica IGHTS. This application is subje | e correspondence address application. If not included tion will be mailed in due course. THIS | |
| 1. This communication is responsive to <u>12/27/2007</u> . | | | |
| 2. The allowed claim(s) is/are <u>17,20,23,24 and 35-39</u> . | | | |
| 3. ☐ Acknowledgment is made of a claim for foreign priority unas a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have 3. ☐ Copies of the certified copies of the | e been received. e been received in Application No |) | |
| International Bureau (PCT Rule 17.2(a)). * Certified copies not received: | | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submin INFORMAL PATENT APPLICATION (PTO-152) which give | MENT of this application. itted. Note the attached EXAMIN | ER'S AMENDMENT or NOTICE OF | |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must | st he submitted | | |
| (a) ☐ including changes required by the Notice of Draftspers | | TO-948) attached | |
| 1) ☐ hereto or 2) ☐ to Paper No./Mail Date | | , | |
| (b) including changes required by the attached Examiner Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in the same paper. | .84(c)) should be written on the dra | awings in the front (not the back) of | |
| DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT | sit of BIOLOGICAL MATERIA | L must be submitted. Note the | |
| Attachment(s) 1. □ Notice of References Cited (PTO-892) | 5. □ Notice of Inform | al Patent Application | |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. Interview Summ | | |
| 3. ☑ Information Disclosure Statements (PTO/SB/08), | Paper No./Mail 7. ⊠ Examiner's Ame | Date | |
| Paper No./Mail Date 12/27/2007 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material | | ement of Reasons for Allowance | |
| | | | |

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EXAMINER'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 12/27/2007 has been entered.

- 2. Claims 17,20,23,24 and 35-39 are currently pending and are present for examination.
- 3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Xie Zhou on 2/26/08.

The application has been amended as follows:

In the claims—

17. A method of treating an allergic disorder in a mammal, comprising administering to said mammal a therapeutically effective amount of a T Cell Cytokine Receptor (TCCR) agonist antibody or TCCR binding fragment thereof, a bispecific TCCR agonist antibody, a heteroconjugate TCCR agonist antibody, or a TCCR agonist diabody comprising two TCCR antigen binding sites, wherein any of said antibodies or fragment comprises two or more TCCR antigen binding sites.

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REASONS FOR ALLOWANCE

- 4. The following is an examiner's statement of reasons for allowance: Prior art of record teaches that administering agonist ligands for the receptor recited herein as "TCCR" is useful for stimulating cell-mediated immunity and for stimulating lymphocyte proliferation (US Patent 5,792,850 (Baumgartner). The '850 patent also teaches that bivalent antibodies may be agonists. Based on the Baumgartner disclosure, administration of a TCCR agonist with the expectation of a generalized stimulation of the immune response was known in the art before the instant application was filed. Furthermore, given that agonist antibodies must bind to at least two sites to ensure receptor aggregation, it would be predictable that constructs that bind two or more sites on TCCR would work as agonists. None of the prior art of record teaches, however, that an effect of TCCR activation is to shift the Th1/Th2 balance so as to specifically benefit a patient with an allergic disorder. Therefore, the prior art does not teach or fairly suggest the selection of a mammal in need of treatment for an allergic disorder as required by the instant claims. The predicted benefit of TCCR activation in this context is based on the understanding of the physiological role of TCCR first disclosed in the instant application.
- 5. The purpose of the Examiner's amendment herein is to provide additional clarity. The amended claim explicitly indicates the understood scope of the claim previously allowed.
- 6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Application/Control Number: 10/088,950

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG Art Unit 1647 7 March 2008

/Manjunath N. Rao, / Supervisory Patent Examiner, Art Unit 1647